

9-valent HPV Vaccine Criteria for Use October 2015

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. The clinician should utilize this guidance and interpret it in the clinical context of the individual patient. Individual cases that are outside the recommendations should be adjudicated at the local facility according to the policy and procedures of its P&T Committee and Pharmacy Services. The Product Information should be consulted for detailed prescribing information.

Exclusion Criteria *If the answer to ANY item below is met, then the patient should NOT receive vaccine.*

- ☐ Female or male greater than 26 years of age
- ☐ Pregnant or may be pregnant
- ☐ Individuals with a history of immediate hypersensitivity to yeast or other components of the vaccine
- ☐ Moderate or severe acute illnesses (vaccination should be deferred until after the patient improves)

Inclusion Criteria *The answers to one of the following must be fulfilled in order to meet criteria.*

- ☐ Females 9-26 years of age if unvaccinated or not completed 3-dose HPV series.
- ☐ Males 9-26 years of age if unvaccinated or not completed 3-dose HPV series.

Refer to Issues for Consideration for information for persons who started an HPV vaccination series with quadrivalent or bivalent HPV vaccine.

Dosage and Administration

9-valent Human Papillomavirus vaccine is administered intramuscularly as 3 separate 0.5 ml doses. The first dose is followed by 2 additional doses given at 2 and 6 months after the initial dose.

Issues for Consideration

- For females, ACIP recommends routine vaccination of females aged 11 or 12 years and catch-up vaccination for females aged 13 through 26 years old.
- For males, ACIP recommends routine vaccination of males aged 11 or 12 years and catch-up vaccination for males aged 13 through 21 years old with quadrivalent HPV vaccine. For males 22 – 26 years old, ACIP recommends quadrivalent HPV vaccine for persons 1) immunocompromised as a result of infection (including HIV infection), disease, or medication who did not get any or all doses when they were younger and 2) men who have sex with men (MSM) who did not get any or all doses when they were younger as they might especially benefit from vaccination to prevent condyloma and anal cancer. In addition, males aged 22 through 26 years may be vaccinated (i.e. permissive recommendation).
- **Information for persons who started an HPV vaccination series with quadrivalent or bivalent HPV vaccine:**
 - If a series was started with quadrivalent HPV vaccine or bivalent HPV vaccine, can it be completed with 9-valent HPV vaccine?** Yes, ACIP recommendations state that 9-valent HPV vaccine may be used to continue or complete a series started with a different HPV vaccine product.
 - Are additional 9-valent HPV vaccine doses recommended for a person who started a series with quadrivalent or bivalent HPV vaccine and completed the series with one or two doses of 9-valent HPV vaccine?** There is no ACIP recommendation for additional 9-valent HPV vaccine doses for persons who started the series with quadrivalent or bivalent HPV vaccine and completed the series with 9-valent HPV vaccine.
 - Refer to [CDC's Supplemental information and guidance for vaccination providers regarding use of 9-valent HPV vaccine](#) for more specific details.
- It is not recommended to test for HPV infection prior to vaccination as testing only indicates current but not past infection.
- The 9-valent Human Papillomavirus vaccine can be administered to persons with a history of genital warts, abnormal Papanicolaou test, or positive HPV DNA test, because these conditions are not evidence of prior infection with all vaccine HPV types.

- The importance of continued routine cervical cancer screening with Pap smear tests should be reinforced in both vaccinated and unvaccinated women.
 - Syncope (i.e., vasovagal or vasodepressor reaction) has been reported following vaccination and may result in falling and traumatic injury; health care providers should observe vaccinee for 15 minutes after administration. These falls and injuries may be prevented by having vaccinee seated or lying down for 15 minutes following vaccination, and closely observing vaccinee for signs and symptoms that may occur before fainting including paleness, sweating, dizziness, ringing in ears or vision changes. Syncope may be associated with tonic-clonic movements or other seizure-like activity; the activity is usually transient and typically responds to restoring cerebral perfusion by maintaining a supine or Trendelenburg position.
 - VHA Clinical Guidance Statement on HPV Immunization are available on VHA National Center Health Promotion and Disease Prevention (NCP) intranet site http://vaww.prevention.va.gov/Guidance_on_Clinical_Preventive_Services.asp
 - Patient information related to the 9-valent HPV vaccine is available through CDC.
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